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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/687,327

Applicant(s)

BOGA ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-60 and 63-82 is/are pending in the application.
- 4a) Of the above claim(s) 27-59 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60 and 63-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 27-60 and 63-82 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/9/07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. All previously pending claims have been canceled. Claims 27-59 stand withdrawn from consideration for reasons of record, and new claims 60-82 have been added; claim 82 being directed to a non-elected
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Continued Examination Under 37 CFR 1.114*

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2007 has been entered.

#### *Information Disclosure Statement*

4. The information disclosure statement filed July 9, 2007 has been considered.

#### *Objections/Rejections Withdrawn*

5. **Specification** The amendment filed December 7, 2006 objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, the amendment to the Specification at page 8, line 15, which inserted the phrase "source of urea" has been obviated through deletion of this phrase. n.
6. **Claim Rejections - 35 USC § 112** Claims 60-81 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement by amendment of the Specification at page 5, line 18 which redefines the R, R', R" groups, provides support for the claim limitations in the new submitted claims. R" for Michler's Hydrol has been amended to be "H" and to no longer be (CH<sub>3</sub>)<sub>2</sub>NC<sub>6</sub>H<sub>5</sub>- and having claim 60 and dependent claims (61-81) recite **both** "H" and "(CH<sub>3</sub>)<sub>2</sub>NC<sub>6</sub>H<sub>5</sub>-"; has been obviated by canceling this combination of claim limitations in independent claim 60, and dependent claim 61-62.
7. Rejections under Second paragraph of 35 U.S.C. 112 Claim 62 and Claim 72 not having sufficient antecedent basis have been obviated by cancellation of the claim, and amendment to depend from a different claim, respectively.
8. **Withdrawn, Claim Rejections - 35 USC § 102** Claims 60, 62, 66, 70-76 and 79 rejected under 35 U.S.C. 102(b) as being anticipated by Bather (US Pat. 4,844,867) is herein withdrawn in light of this species being canceled from the claims.
9. **Withdrawn**, Claims 60, 62, 66, 73 and 75 rejected under 35 U.S.C. 102(e) as being anticipated by Scaringe et al (US Pat. 6,825,040 is herein withdrawn in light of this species being canceled from the claims.

***Response to Arguments***

Please Note: Rejections Maintained will be addressed; rejections withdrawn will not be discussed herein.

**10.** Maintained, Double Patenting: The rejection of claims 60-81 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-48 of copending Application No. 10/687,270 was not addressed by Applicant and therefore maintained for reasons of record.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 103***

**11.** Claim 60, 66, 71-72, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunstar, KK (JP 6215177 (English abstract) in view of US Pat. 5,174,959.

Sunstar describe a composition comprising a breath testing device (see abstract, paragraph 2 “The deg of foul breath correlates with the amt. of volatile sulphides”), the device comprising a visual indicating agent (4,4’-bis-dimethyl-aminodiphenyl carbino (BDC-0H), which is also known as Michler’s hydrol, impregnated into a filter paper, which results in a test paper with detecting/indicating agent solution and functions as a breath collection device (the device being the test paper in association with the indicating agent). Sunstar differs from the instantly claimed invention by failing to refer to this composition as a kit, or to formulate the device into kit form.

US Pat. 5,174,959 describes a kit (see claims) for monitoring breath components in an analogous art for the purpose of determining levels of various components in a persons breath.

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It would have been obvious to the person of ordinary skill in the art at the time the invention was made to formulate the breath collection/breath testing device of Sunstar into kit form as taught by US Pat. 5,174,959 because US Pat. 5,174,959 teaches kits to be compositions, which comprise breath collection and detection devices (see claim 12), and Sunstar describes such a composition that comprises both breath collection (filter paper with detecting agent solution) and visual indicating agent devices (Michler's hydrol).

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of obtaining kits for testing breath components as taught by US Pat. 5,174,959 the comprise breath collecting/testing devices with a Michler's hydrol visual indicating agent as taught by Sunstar because Sunstar teaches a testing device with increased sensitivity (raises sensitivity, paragraph 1), which readily shows a color change of Michler's hydrol (BDC-OH) which is estimated by eyes or absorbance and relates to the degree of the detected component present in the breath and US Pat. 5,174,959 teaches kits provide means for carrying out the desired tests on breath through measuring a color change.

12. Claims 60,66, 73, 75, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delente (US Pat. 5,432,094) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960.

Delente teaches and shows the formulation of a kit (see figure 4) that comprises both a breath collection device (see front of patent and figure 4, and claims), and visual indicating agent (color indicator; see figure 2), as well as the importance of measuring a particular chemical compound in the breath (see col. 1, lines 20-39), to include ammonia (see col. 1, line 23), but

differs from the instantly claimed invention by failing to show the visual indicating agent to be Michler's hydrol.

Arai et al (US PG Pub 2002/0068364) teach visual indicating agents for detection of ammonia (see title, [002]), in an analogous art for the purpose of showing triarylmethane dye precursors to function as indicator agents for ammonia (see [0011]) when formulating ammonia detection devices. US Pat. 4,407,960 teaches triarylmethane dyes to include Michler's hydrol in an analogous art for the purpose of showing functional equivalents within the genus of triarylmethane dyes which will serve as visual indicating agents when detecting chemical components present in vapor and function as color change indicators (see Brief summary paragraph 19, 23 and Detailed Description paragraph 3, 41 and 53).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the kit of Delente to include visual indicator agents for the detection of ammonia as taught by Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960 in breath as suggested by Delente because Delente teaches ammonia is useful and known to serve in diagnostic techniques and Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960 both teach triarylmethane dyes, and US Pat. 4,407,960 shows Michler's hydrol to be a member of triarylmethane dyes that can serve as visual indicator agents for components in a gaseous sample and Arai et al teach triarylmethane dyes to detect ammonia in a sample.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining a kit that comprises Michler's hydrol that serves as breath testing device together with a breath collecting device because Delente teaches a kit that comprises both a breath testing device and a breath collecting device, teaches ammonia to serve as a diagnostic component present in breath

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(Delente, col. 1), and Arai et al and US Pat. 4,407,960 teach a genus of triarylmethane dyes, of which Michler's hydrol is a member, to successfully detect ammonia in a sample.

Delente in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960 obviate the instantly claimed invention as now claimed.

13. Claims 60, 63-69, 71-81, are rejected under 35 U.S.C. 103 as being obvious over Pan (US PG-Pub 2004/0077093) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960.

14. Pan describes the instantly claimed invention directed to a kit (page 2, [0022, kit] and [0013] "breath handler and detection unit") that comprises both a breath collection device (ammonia) and visual indicating agent (see Figure 2, for detection of *Helicobacter pylori* (see [0010, page 1]) for reacting with ammonia (see [0060]) for determining the presence or absence of *H. pylori* infection (see [0008, and 0010, page 1]).

15. The kit/device is compiled and comprises a:

**Instant claim 60:** breath/gas collection device [0041, page 4] and an indicating agent (see Figure all figures, Figure 2; [0013] and [0060])

**Instant claims 63-64:** sensitive to ammonia to a concentration within the ranges of about 20 to 500 parts per million and about 50 to about 400 parts per million (see Figure 7, 0.1 to 100 ppm)

**Instant claim 60 & 66:** a substrate (polymeric material and a dye associated with the polymeric material (see page 2, [0011]) with a visual indicating agent disposed therein (also see [0057 "embed or bind the dye to the pores of the polymer"; and [0012]), the pores being from about 0.2 microns to about 9 micrometers, preferably about 2.5 microns or less (see page 5 [0051]) and the dye indicator being in a shape of beads [0056] (microns is equivalent to nanometers and therefore have a size less than about 100 nanometers

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**Instant claim 67-69:** nanoparticles ( “beads” see [0056, page 5]; microbead layer, page 4, [0043], transferred to collecting apparatus, and ammonia gas is then determined; pore size of the polymer can range from about 2.5 microns to about 1 micron )

**Instant claim 73:** wherein the substrate is located within a passage of a carrier portion of the breath collection device (see Figure 2, #127; figure 5, #227)

**Instant claim 74-76:** a carrier portion that comprises at least one open end (tube shape, see Figure 2, 4 and 5) and is a cylindrical structure , and also comprises a carrier portion that is substantially flattened (see figure 5, #205)

**Instant claim 77:** wherein the carrier portion is connected to a balloon (see page 4, [0041] “the subject may exhale into a balloon and the contents of the balloon may be directly or indirectly transferred to a sensor for analysis”), wherein the direct transfer of the exhaled breath would be connected to the carrier portion for contact with the indicator portion of the ammonia detection device.

**Instant claim 78:** wherein the substrate covers an end of a carrier portion of the breath collecting device (see Figure 5, where the substrate (#227) covers a portion of the carrier (#205) at near the left end of the collection device (#201)

**Instant claim 79:** the visual indicating agent is applied to the substrate as a solution (see page 5 [0058 “dye can be blended or mixed into the casting solution”]).

**Instant claim 80-81:** the concentration of the dye is within the range of about 0.001 to about 15 % wt/wt of the solution, and from about 0.005 to about 2% wt/wt (see page 5 [0058 “at least about 0.1% by weight of the dye in a solution”])

Pan (US PG-Pub 2004/0077093) teach and show a kit that comprises a breath collection device together with an indicator dye for detecting ammonia in an exhaled breath, or gas biological sample and teaches [0060] “Any dye that is sensitive to and responds to changes in the



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amount of ammonia that permeates the pores of the polymer may be employed. In a preferred embodiment, the dye is a pH sensitive dye”, but differs from the instantly claimed invention by failing to show the ammonia pH sensitive dye to be Michler’s hydrol. (also known as 4,4’-bis(dimethylamino)-benzhydrol, a triarylmethane dye).

Arai et al (US PG Pub 2002/0068364) teach visual indicating agents for detection of ammonia (see title, [002]) and comparison of the test result with a standard hue for to the visual indicating agent (see [0031, last line of paragraph] in an analogous art for the purpose of showing triarylmethane dye precursors to function as indicator agents for ammonia (see [0011]) when formulating ammonia detection devices and means for visually detecting ammonia (see page 3, [0031, second line from bottom]). US Pat. 4,407960 teaches triarylmethane dyes to include Michler’s hydrol in an analogous art for the purpose of showing functional equivalents within the genus of triarylmethane dyes which will serve as visual indicating agents when detecting chemical components present in a gaseous sample (see color change indicators Brief summary paragraph 19, 23 and Detailed Description paragraph 3, 41 and 53).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the kit of Pan that comprises an ammonia indicator dye with the ammonia indicator dye of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960 because both Pan and Arai et al are directed to detection of ammonia (amine/amide containing samples) with a pH sensitive color indicator and Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960 teach triarylmethane dyes, which include Michler’s hydrol to function as indicator dyes for ammonia, the dyes serving as inexpensive indicators in detection devices.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of detecting ammonia with the indicator dyes of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960 formulated

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into the kit of Pan, because Pan teaches that any indicator dye that will react with ammonia to produce a color change may be employed as the indicator dye in the ammonia detection kit device, and Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960 teach Michler's hydrol and triarylmethane dyes to function as indicator dyes which would serve to detect ammonia by producing a color change when contacted with ammonia. Pan in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960 obviate the instantly claimed invention as now claimed.

16. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pan (US PG-Pub 2004/0077093) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960, as applied to claims 60, 63-69, 71-81 above, further in view of US Pat. 7,052,854.

17. Pan (US PG-Pub 2004/0077093) in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407,960 teach a kit that comprises a breath collection device, a breath testing device together with a visual indicating agent for ammonia, the indicating agent being Michler's hydrol, the indicating agent being associated with nanoparticles, but differs from the instantly claimed invention by failing to show the nanoparticles to be silica or alumina.

US Pat. 7,052,854 teach and show nanoparticles of silica and alumina with a color indicator attached on the surface of the nanoparticles for detecting the biomarker ammonia in an analogous art for the purpose of defining nanostructure-based assemblies in combination with sensor technology to provide an efficient and accurate means for identifying the presence of a target analyte/biomarker in a sample of bodily fluid (see title, abstract, paragraphs detailed description [14, 53 and 68])

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the nanoparticles of Pan with the alumina or silica nanoparticles

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of US Pat. 7,052,854 because US Pat. 7,052,854 teaches the nanoparticles serve as a surface for immobilizing the detection reagent, and also serve to define nanostructure-based assemblies that are compatible with sensor technology which is an efficient and accurate means for identifying the presence of a target analyte/biomarker, specifically ammonia.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of obtaining an ammonia detection kit that comprises a breath collection device and breath testing device that comprises nanoparticles as describe, taught and shown in Pan in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960, wherein the nanoparticles are alumina or silica as taught by US Pat. 7,052,854 because US Pat. 7,052,854 and Pan both utilize nanoparticles to detect ammonia and US Pat. 7,052,854 teach alumina or silica nanoparticles are compatible and readily incorporated into sensor technology which is an efficient and accurate means for identifying the presence of a biomarker, specifically ammonia in a sample of bodily fluid .

Pan in view of Arai et al (US PG Pub 2002/0068364) and US Pat. 4,407960, and further in view of US Pat. 7,052,854 obviate the instantly claimed invention as now claimed.

### ***Conclusion***

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Various references have been cited to show indicators, and detection devices for ammonia.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp  
September 11, 2007

MARK NAVARRO  
PRIMARY EXAMINER

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